Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: May 8, 2013

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: Chang Kwung Recall

SUGGESTED ACTION: **Unclassified Recall; after being notified by the US FDA that analytical testing found the Lightning Rod Capsules to contain an analogue of Sildenafil. Sildenafil is the active ingredient in an FDA-approved drug used for the treatment of male Erectile Dysfunction (ED), making Lightning Rod Capsules an unapproved new drug; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled products may have been distributed in the State of Indiana. The recalled products are sold nationwide via internet in 3 capsule count and 12 capsule count bottles between August 2012 and May 3, 2013. Information is provided in case of consumer inquiry.

****

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Chang Kwung Issues A Voluntary Nationwide Recall of Lightning Rod Capsules Due to Undeclared Ingredient

Contact:
Consumer
Ralph Ceglia
747-444-1843
rxxxone777@gmail.com

FOR IMMEDIATE RELEASE - May 7, 2013 - Chang Kwung announced today that it is conducting a voluntary nationwide recall of the company's dietary supplements sold under the brand name Lightning Rod 500 mg per capsule packaged in 3-count, UPC 6 89076 20257 2 and 12-count bottles, UPC 6 89076 20297 8.

Chang Kwung is conducting a voluntary recall after being notified by the US FDA that analytical testing found the Lightning Rod Capsules to contain an analogue of Sildenafil. Sildenafil is the active ingredient in an FDA-approved drug used for the treatment of male Erectile Dysfunction (ED), making Lightning Rod Capsules an unapproved new drug. The active drug ingredient is not listed on the label for this product. Use of this product may pose a threat to consumers because the analogue may interact with nitrates found in some prescription drugs (such as nitroglycerin) and may lower blood pressure to dangerous levels. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. ED is a common problem in men with these conditions, and consumers may seek these types of products to enhance sexual performance. To date, the firm has not received any reports of adverse events related to this recall or is aware of any illnesses associated with this product.

Lightning Rod capsules are sold over the counter as a dietary supplement marketed for male sexual enhancement. It is sold nationwide via internet in 3 capsule count and 12 capsule count bottles between August 2012 and May 3, 2013.

Chang Kwung Inc. advises any customer in possession of Lightning Rod Capsules matching the description above, return any unused product, for a full refund, to the company directly. Consumers with questions regarding this recall can call 747-444-1843, Monday through Friday 9:00 AM to 5:00 PM PST, for instructions on the return and refund process. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product.

Chang Kwung is committed to improving its products and avoiding future recall issues by sourcing higher quality raw ingredients and expanding testing. Chang Kwung promises its customers the highest possible quality and welcomes the recall process as further evidence of our commitment to our brands, products and consumers.

Any adverse reactions or quality problems experienced with the use of these products may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online: http://www.fda.gov/MedWatch/report.htm [1]
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: http://www.fda.gov/MedWatch/getforms.htm[2].
  Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

RSS Feed for FDA Recalls Information[3] [what's this?[4]]

Photo: Product Labels[5]